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6 Attorneys for Defendant
7 MERCK & CO., INC.

8
9 UNITED STATES DISTRICT COURT
10 EASTERN DISTRICT OF CALIFORNIA

11 ERNESTINE HIGET,

CASE NO. 2:07-CV-01872-LKK-EFB

12 Plaintiff,

13 DEFENDANT MERCK & CO., INC.'S
14 ANSWER TO COMPLAINT

15 MERCK & CO., INC., and
16 DOES 1-25, inclusive

DEMAND FOR JURY TRIAL

17 Defendants.

20
21 Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned
22 attorneys, hereby answers those allegations of Plaintiff's Complaint ("Complaint")
23 directed to it. To the extent the allegations of any paragraph are directed at defendants
24 other than Merck, Merck is not required to respond to those allegations. To the extent a
25 response is deemed necessary, Merck states that it denies all such allegations, except
26 those that are specifically admitted below. Merck denies all allegations set forth in the
27 Complaint directed at Merck except to the extent such allegations are specifically
28 admitted below:

I. JURISDICTION AND VENUE

2 1. The allegations of the first sentence of Paragraph 1 are conclusions of law
3 to which no response is required. To the extent that a response is required, Merck
4 denies each and every allegation of the first sentence of Paragraph 1. As to the
5 allegations of the second sentence of Paragraph 1, Merck is without knowledge or
6 information sufficient to form a belief as to these allegations, except that Merck admits
7 that it is a corporation organized under the laws of the State of New Jersey with its
8 principal place of business in New Jersey. As to the allegations in the third sentence of
9 Paragraph 1, Merck admits for jurisdictional purposes only, that Plaintiff seeks in
10 excess of \$75,000.

11 2. The allegations of the first sentence of Paragraph 2 are conclusions of law
12 to which no response is required. To the extent a response is required, Merck denies the
13 allegations of Paragraph 2.

3. The allegations of Paragraph 3 do not require a response.

II. PARTIES

16 4. Merck is without knowledge or information sufficient to form a belief as to
17 the allegations of Paragraph 4.

18 5. Merck denies each and every allegation of Paragraph 5, except admits that
19 it is a New Jersey corporation with its principal place of business in New Jersey.

20 6. Merck admits that it is registered to do business in the States of California
21 and New York.

22 7. Merck is without knowledge as to what is meant by the phrase “regularly
23 transacted,” so the allegations in Paragraph 7 are denied.

24 8. Merck denies each and every allegation of Paragraph 8, except that it
25 admits that Merck manufactured, marketed, and distributed the prescription medicine
26 FOSAMAX® in accordance with its approved prescribing information. Merck denies
27 any allegations in Paragraph 8 inconsistent with that prescribing information and
28 respectfully refers the Court to the Physician's Desk Reference ("PDR") for

1 FOSAMAX® for its actual language and full text.

2 9. Merck admits only that it distributed FOSAMAX® for prescription in
3 accordance with its approved prescribing information and denies any allegations in
4 Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers
5 the Court to the PDR for FOSAMAX® for its actual language and full text. Except as
6 expressly admitted herein, Merck denies the remaining allegations of Paragraph 9.

7 10. Merck is without knowledge as to what is meant by the phrase "substantial
8 revenue," so the allegations in Paragraph 10 are denied.

9 11. Merck is without knowledge as to what is meant by "consequences," so the
10 allegations in Paragraph 11 are denied.

11 **III. SUMMARY OF THE CASE**

12 12. Merck denies each and every allegation of Paragraph 12, except that it
13 admits that Merck manufactured, marketed, and distributed the prescription medicine
14 FOSAMAX® for prescription in accordance with its approved prescribing information.

15 13. Merck denies each and every allegation of Paragraph 13.

16 14. Merck denies each and every allegation of Paragraph 14.

17 15. Merck denies each and every allegation of Paragraph 15.

18 16. Merck denies each and every allegation of Paragraph 16.

19 **IV. FACTUAL BACKGROUND**

20 17. Merck denies each and every allegation of Paragraph 17, except that it
21 admits that Merck manufactured, marketed, and distributed the prescription medicine
22 FOSAMAX® for prescription in accordance with its approved prescribing information.

23 18. Merck denies each and every allegation of Paragraph 18, except that
24 Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture
25 and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription
26 medication approved by the FDA for prescription in accordance with its approved
27 prescribing information. Merck denies any allegations in Paragraph 18 inconsistent
28 with that prescribing information.

1 19. Merck admits only that FOSAMAX® is a prescription medication
2 approved by the FDA for prescription in accordance with its approved prescribing
3 information and denies any allegations in Paragraph 19 inconsistent with that
4 prescribing information. Merck also refers the Court to the prescribing information for
5 Aredia and Zometa, and denies any allegations in Paragraph 19 with respect to Aredia
6 and Zometa inconsistent with that prescribing information.

7 20. Merck admits only that some bisphosphonates contain nitrogen and some
8 do not and that FOSAMAX® is a prescription medication approved by the FDA for
9 prescription in accordance with its approved prescribing information. Merck denies any
10 allegations in Paragraph 20 inconsistent with that prescribing information. Merck
11 respectfully refers the Court to the PDR for FOSAMAX® for its actual language and
12 full text. Merck also refers the Court to the prescribing information for Aredia,
13 Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in
14 Paragraph 20 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid
15 inconsistent with that prescribing information. Merck denies the remaining allegations
16 of Paragraph 20.

17 21. Merck denies each and every allegation of Paragraph 21.
18 22. Merck denies each and every allegation of Paragraph 22.
19 23. Merck denies each and every allegation of Paragraph 23.
20 24. Merck is without knowledge or information sufficient to form a belief as to
21 the allegations of Paragraph 24.

22 25. Merck denies each and every allegation of Paragraph 25.
23 26. Merck denies each and every allegation of Paragraph 26.
24 27. Merck denies each and every allegation of Paragraph 27.
25 28. Merck denies each and every allegation of Paragraph 28.
26 29. Merck denies each and every allegation of Paragraph 29, except that
27 Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but
28 respectfully refers the Court to said document for its actual language and full text.

30. Merck denies each and every allegation of Paragraph 30.
31. Merck denies each and every allegation of Paragraph 31.
32. Merck denies each and every allegation of Paragraph 32.
33. Merck denies each and every allegation of Paragraph 33, except that

34. Merck is without knowledge as to whether Plaintiff used FOSAMAX®.
Merck denies the remaining allegations in Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck is without knowledge as to whether Plaintiff was prescribed

FOSAMAX®. Merck denies the remaining allegations in Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 38.

39. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

COUNTS

COUNT I: NEGLIGENCE

46. Merck repleads its answers to Paragraphs 1 through and including 45, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

1 47. The allegations in Paragraph 47 are conclusions of law to which no
2 response is required; to the extent that a response is deemed necessary, the allegations
3 are denied and Merck respectfully refers the Court to the relevant legal standard,
4 including any conflict of law rules.

5 48. Merck denies each and every allegation of Paragraph 48, including each
6 and every allegation contained in subparts (a) through (f).

7 49. Merck denies each and every allegation of Paragraph 49.

8 50. Merck denies each and every allegation of Paragraph 50.

COUNT II: STRICT LIABILITY

10 51. Merck repleads its answers to Paragraphs 1 through and including 50, and
11 by this reference hereby incorporates the same herein in this paragraph, and makes the
12 same a part hereof as though fully set forth *verbatim*.

13 52. Merck denies each and every allegation of Paragraph 52, except that it
14 admits that Merck manufactured, marketed and distributed the prescription medicine
15 FOSAMAX® for prescription in accordance with its approved prescribing information
16 and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff
17 alleges he consumed.

18 53. Merck denies each and every allegation of Paragraph 53, except that it
19 admits that Merck manufactured, marketed and distributed the prescription medicine
20 FOSAMAX® for prescription in accordance with its approved prescribing information
21 and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff
22 alleges he consumed.

23 54. Merck is without knowledge or information sufficient to form a belief as to
24 the allegations of Paragraph 54.

25 55. Merck denies each and every allegation of Paragraph 55.

26 | 56. Merck denies each and every allegation of Paragraph 56.

27 57. Merck denies each and every allegation of Paragraph 57.

28 58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

COUNT III: BREACH OF EXPRESS WARRANTY

63. Merck repleads its answers to Paragraphs 1 through and including 62, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

64. Merck denies each and every allegation of Paragraph 64, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

65. Merck denies each and every allegation of Paragraph 65.

66 Merck denies each and every allegation of Paragraph 66.

67. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

COUNT IV: BREACH OF IMPLIED WARRANTY

70. Merck repleads its answers to Paragraphs 1 through and including 99, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

71. Merck denies each and every allegation of Paragraph 71, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

72. Merck denies each and every allegation of Paragraph 72, and respectfully refers the Court to the FDA-approved prescribing information for any and all

representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

73. Merck denies each and every allegation of Paragraph 73.

5 74. Merck lacks knowledge or information sufficient to form a belief as to the
6 truth or falsity of the allegations of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

8 76. Merck lacks knowledge or information sufficient to form a belief as to the
9 truth or falsity of the allegations of Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the
or falsity of the allegations of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

COUNT V: FRAUDULENT MISREPRESENTATION

80. Merck repleads its answers to Paragraphs 1 through and including 79, and
its reference hereby incorporates the same herein in this paragraph, and makes the
a part hereof as though fully set forth *verbatim*.

81. Merck denies each and every allegation of Paragraph 81, including each very allegation contained in subparts (a) through (b).

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

COUNT VI: FRAUDULENT CONCEALMENT

89. Merck repleads its answers to Paragraphs 1 through and including 88, and

1 by this reference hereby incorporates the same herein in this paragraph, and makes the
 2 same a part hereof as though fully set forth *verbatim*.

3 90. Merck denies each and every allegation of Paragraph 90, including each
 4 and every allegation contained in subparts (a) through (b).

5 91. Merck denies each and every allegation of Paragraph 91.

6 92. Merck denies each and every allegation of Paragraph 92.

7 93. Merck denies each and every allegation of Paragraph 93.

8 94. Merck denies each and every allegation of Paragraph 94.

9 95. Merck denies each and every allegation of Paragraph 95.

10 96. Merck denies each and every allegation of Paragraph 96.

GLOBAL PRAYER FOR RELIEF

11 Merck denies that Plaintiff is entitled to any of the relief requested in his
 12 Global Prayer for Relief.

13 WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's
 14 Complaint with prejudice and awarding Merck such other and further relief that the
 15 Court may deem just and proper.

AFFIRMATIVE DEFENSES

16 Discovery and investigation may reveal that any one or more of the following
 17 additional defenses should be available to Merck in this matter. Merck, therefore,
 18 asserts said additional defenses in order to preserve the right to assert them. Upon
 19 completion of discovery, and if the facts warrant, Merck may withdraw any of these
 20 additional defenses as it may deem appropriate. Further, Merck reserves the right to
 21 amend its Answer to assert additional defenses, cross-claims, counterclaims, and other
 22 claims and defenses as discovery proceeds. Further answering and by way of additional
 23 defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

24 Each and every claim asserted or raised in the Complaint is barred by the
 25 applicable statute of limitations and is otherwise untimely.

1 **SECOND AFFIRMATIVE DEFENSE**

2 The Complaint fails to state a claim upon which relief can be granted.

3 **THIRD AFFIRMATIVE DEFENSE**

4 Each and every claim asserted or raised in the Complaint is barred by the
5 doctrines of estoppel, waiver or statutory and regulatory compliance.

6 **FOURTH AFFIRMATIVE DEFENSE**

7 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon
8 information and belief, such injuries or losses were caused in whole or in part through
9 the operation of nature or other intervening cause or causes.

10 **FIFTH AFFIRMATIVE DEFENSE**

11 To the extent that Plaintiff asserts claims based on Merck's adherence to and
12 compliance with applicable state laws, regulations and rules, such claims are preempted
13 by federal law under the Supremacy Clause of the United States Constitution.

14 **SIXTH AFFIRMATIVE DEFENSE**

15 To the extent that Plaintiff asserts claims based upon an alleged failure by Merck
16 to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®,
17 such claims are barred under the learned intermediary doctrine because Merck has
18 discharged its duty to warn in its warnings to the prescribing physician.

19 **SEVENTH AFFIRMATIVE DEFENSE**

20 If Plaintiff has sustained injuries or losses as alleged in the Complaint, such
21 injuries or losses were cause in whole or in part by the contributory negligence of the
22 allegedly injured Plaintiff.

23 **EIGHTH AFFIRMATIVE DEFENSE**

24 Any liability that might otherwise be imposed upon this Defendant is subject to
25 reduction by the application of the doctrine of comparative fault.

26 **NINTH AFFIRMATIVE DEFENSE**

27 If Plaintiff has sustained injuries or losses as alleged in the Complaint, such
28 injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and

1 willfully assumed the risk of any injury as the result of the consumption of,
 2 administration of, or exposure to any medicine or pharmaceutical preparation
 3 manufactured or distributed by Merck or other manufacturer.

4 **TENTH AFFIRMATIVE DEFENSE**

5 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon
 6 information and belief, such injuries and losses were caused by the actions of persons
 7 not having real or apparent authority to take said actions on behalf of Merck and over
 8 whom Merck had no control and for whom Merck may not be held accountable.

9 **ELEVENTH AFFIRMATIVE DEFENSE**

10 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon
 11 information and belief, such injuries and losses were proximately caused by Plaintiff's
 12 misuse or abuse of FOSAMAX®.

13 **TWELFTH AFFIRMATIVE DEFENSE**

14 If Plaintiff has sustained injuries or losses as alleged in the Complaint, such
 15 injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic
 16 and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions,
 17 subsequent medical conditions or natural courses of conditions for which this
 18 Defendant is not responsible.

19 **THIRTEENTH AFFIRMATIVE DEFENSE**

20 To the extent that Plaintiff relies upon any theory of breach of warranty, such
 21 claims are also barred for lack of timely notice of breach and/or lack of privity.

22 **FOURTEENTH AFFIRMATIVE DEFENSE**

23 Plaintiff's claims are barred in whole or in part under the applicable state law
 24 because FOSAMAX® was subject to and received pre-market approval by the FDA
 25 under 52 Stat. 1040, 21 U.S.C. § 301.

26 **FIFTEENTH AFFIRMATIVE DEFENSE**

27 Plaintiff's claims are barred in whole or in part because the product at issue was
 28 made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have
ANSWER TO COMPLAINT 12

1 reduced the alleged risk without substantially impairing the reasonably anticipated and
2 intended function of FOSAMAX®.

3 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

4 Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

5 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

6 Plaintiff's claims are barred in whole or in part because Merck's conduct
7 conforms with medical knowledge.

8 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

9 With respect to each and every cause of action, Plaintiff is not entitled to
10 recovery for strict liability because Plaintiff cannot state claims founded in strict
11 liability because, among other things, comments j and k to Section 402A of the
12 Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of
13 action.

14 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

15 All activities of Merck as alleged in the Complaint were expressly authorized
16 and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to
17 unfair or deceptive practices are barred.

18 **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

19 With respect to each and every cause of action, Plaintiff is not entitled to recover
20 because if the product involved was unsafe, which Merck denies, then it was
21 unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the
22 product exceeded any apparent risk given the scientific knowledge available when the
23 product was marketed.

24 **TWENTY-NINTH AFFIRMATIVE DEFENSE**

25 Merck's advertisements and labeling with respect to the products which are the
26 subject matter of this action were not false or misleading and, therefore, constitute
27 protected commercial speech under the applicable provisions of the
28 Constitution of the United States and the Constitution of California.

1 **THIRTIETH AFFIRMATIVE DEFENSE**

2 The public interest in the benefit and availability of the product which is the
3 subject matter of this action precludes liability for risks, if any, resulting from any
4 activities undertaken by this Defendant, which were unavoidable given the state of
5 human knowledge at the time those activities were undertaken. With respect to
6 Plaintiff's claims, if it is determined there is a risk inherent in the product which is the
7 subject matter of this action, then such risk, if any, is outweighed by the benefit of the
8 product.

9 **THIRTY-FIRST AFFIRMATIVE DEFENSE**

10 At all times relevant herein, any product which is the subject matter of this action
11 manufactured and distributed by Merck in any state in the United States was
12 manufactured and distributed in a reasonable and prudent manner based upon available
13 medical and scientific knowledge and further was processed and distributed in
14 accordance with and pursuant to all applicable regulations of the FDA.

15 **THIRTY-SECOND AFFIRMATIVE DEFENSE**

16 With respect to each and every purported cause of action, the acts of Merck were
17 at all times done in good faith and without malice.

18 **THIRTY-THIRD AFFIRMATIVE DEFENSE**

19 To the extent there were any risks associated with the use of the product which is
20 the subject matter of this action which Merck knew or should have known and which
21 gave rise to a duty to warn, Merck at all times discharged such duty through appropriate
22 and adequate warnings in accordance with federal and state law.

23 **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

24 Plaintiff has not sustained an ascertainable loss of property or money.

25 **THIRTY-FIFTH AFFIRMATIVE DEFENSE**

26 Plaintiff has not suffered any actual injury or damages.

27 **THIRTY-SIXTH AFFIRMATIVE DEFENSE**

28 Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

If Plaintiff have sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of Plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by *Li v. Yellow Cab Company* and *America Motorcycle Association v. Superior Court*. Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

FORTY-FIRST AFFIRMATIVE DEFENSE

The asymptomatic plaintiff lacks standing because they have suffered no damages and no injury-in-fact.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

1 **FORTY-FOURTH AFFIRMATIVE DEFENSE**

2 Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely
3 on such warranties and the claims are otherwise barred for lack of timely notice, lack of
4 privity and/or because the alleged warranties were disclaimed.

5 **FORTY-FIFTH AFFIRMATIVE DEFENSE**

6 To the extent that Plaintiff asserts claims based on Merck's adherence to and
7 compliance with applicable state laws, regulations and rules, such claims are preempted
8 by federal law under the Final Rule, Requirements on Content and Format of Labeling
9 for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269
10 (January 24, 2006).

11 **PRAYER FOR RELIEF**

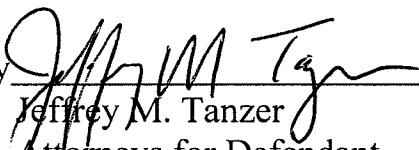
12 WHEREFORE, Merck prays as follows:

- 13 1. That Plaintiff takes nothing by the Complaint;
- 14 2. That this action be dismissed with prejudice;
- 15 3. That Merck be awarded its costs of suit herein, and its attorney's fees to
the extent provided for by statute or contract;
- 16 4. For such other and further relief as the Court deems just and proper.

17
18 Dated: October 3, 2007

19
20 VENABLE LLP
21 DOUGLAS C. EMHOFF
22 JEFFREY M. TANZER

23
24 By



25 _____
26 Jeffrey M. Tanzer
27 Attorneys for Defendant
28 Merck & Co., Inc.

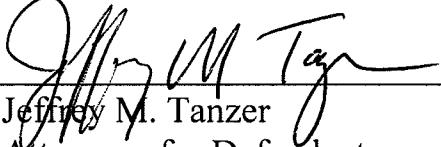
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DEMAND FOR JURY TRIAL
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5 Merck demands a trial by jury as to all issues so triable.
6
7

8 Dated: October 3, 2007
9
10

11 VENABLE LLP
12 DOUGLAS C. EMHOFF
13 JEFFREY M. TANZER
14
15

16 By

17 
18 Jeffrey M. Tanzer
19 Attorneys for Defendant
20 Merck & Co., Inc.
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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is Venable LLP, 2049 Century Park East, Suite 2100, Los Angeles, California.

On October 3, 2007, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

Clayeo C. Arnold
Clifford L. Carter
Kirk J. Wolden
CLAYEO C. ARNOLD, P.C.
608 University Avenue
Sacramento, CA 95825

Attorneys for Plaintiff

- By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.
 - BY MAIL (CCP §1013(a)&(b)):** I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business.
 - BY OVERNIGHT DELIVERY (CCP §1013(c)&(d)):** I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business.

Executed on October 3, 2007 at Los Angeles, California

- (STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

(FEDERAL) I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

ANSWER TO COMPLAINT

18

Jesse Rodriguez